

C. REMARKS

Claims 22-28 have been added in order to define an additional aspect of the present invention.

Claims 16 and 21 stand objected to under 37 CFR 1.121. This objection is respectfully traversed.

The Examiner has taken the position that Claims 16 and 21 do not limit further the independent claims upon which they depend, i.e., Claims 12 and 17, respectively. Claims 12 and 17 are directed to repairing or regenerating blood vessels of the heart (Claim 12) or stimulating or promoting angiogenesis in the heart (Claims 17) of an individual by administering autologous or allogeneic mesenchymal stem cells. Each of Claims 16 and 21 define the mesenchymal stem cells as allogeneic mesenchymal stem cells. Therefore, contrary to the Examiner's assertions, Claims 16 and 21 limit further independent Claims 12 and 17, respectively, upon which they depend. It is therefore respectfully requested that the objection under 37 CFR 1.121 be reconsidered and withdrawn.

Claims 1, 2, 4-10 and 12-21 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite. This rejection is respectfully traversed.

The Examiner has taken the position that it is unlikely that the administration of mesenchymal stem cells by means other than administration to the heart of an individual would produce cardiomyocytes or promote angiogenesis in the heart.

The Examiner is reminded that all that is required by 35 U.S.C. 112, second paragraph, is that the claims point out particularly and claim distinctly the subject matter sought to be patented. (See In Re Borkowski, 164 U.S. P.Q. 642 (C.C.P.A. 1970), at 645.) Applicants and only Applicants are the first to produce cardiomyocytes in the heart, improve ventricular wall motion of the heart or stimulate or promote angiogenesis in the heart of an individual by administering autologous or allogeneic mesenchymal stem cells.

It is clear that Applicants are claiming a method of producing cardiomyocytes in a heart, improving ventricular wall motion of the heart, or stimulating or promoting angiogenesis in the heart of an individual by administering autologous or allogeneic mesenchymal stem cells. Applicants have not indicated that they intend the claims to be of a different scope. Thus, the claims point out particularly and claim distinctly the subject matter that Applicants regard as the invention. (Id., at 645 – 646.)

As in Borkowski, the Examiner cannot study Applicants' disclosure, and then determine whether Applicants' claims are broader than the Examiner's conception of what "the invention" is. (See Borkowski, supra, at 645.) Section 112 does not permit such an approach to claims. Id.

In sum, Applicants have pointed out particularly and claimed distinctly the subject matter that they regard as the invention. It is not within the prerogative of the Examiner to conclude or hold that only a specific means of administration of the mesenchymal stem cells can be included in the claim in order for such claim to comply with 35 U.S.C. 112, second paragraph. In that the claims particularly point out and claim distinctly the subject matter Applicants regard as the invention, the claims are patentable under 35 U.S.C. 112, second paragraph. It is therefore respectfully requested that the rejection under 35 U.S.C. 112 second paragraph, be reconsidered and withdrawn.

Claims 12-21 stand rejected under 35 U.S.C. 112, first paragraph, because the specification lacks an enablement for the full scope of the claimed invention. This rejection is respectfully traversed.

The Examiner has taken the position that the specification does not provide an enabling disclosure for repairing or regenerating blood vessels, or a method of stimulating or promoting angiogenesis in the heart of an individual, or where mesenchymal stem cells are administered by any route to said individual.

The Examiner admits that Examples 6 and 7 state that mesenchymal stem cells were found surrounding, and associated with blood vessels of the heart. The Examiner, however, believes that such localization and association is not synonymous with repair or regeneration of blood vessels or the promotion of angiogenesis.

In Example 7, at Page 20, Applicants state that mesenchymal stem cells were associated with the smooth muscle layer of a blood vessel, and that such cells expressed Factor VIII and VEGF. As stated at Page 20, Factor VIII and VEGF are not expressed by cultured mesenchymal stem cells, but are expressed only after several weeks in the cardiac environment. Thus, contrary to the Examiner's assertions, Applicants have demonstrated that the mesenchymal stem cells did contribute to the formation of blood vessels in the heart.

The Examiner also takes the position that Applicants have demonstrated only the direct injection of mesenchymal stem cells to the heart, and have not demonstrated that administration of the mesenchymal stem cells by other means would be successful.

As noted hereinabove, Applicants have demonstrated that one can administer mesenchymal stem cells to the heart, and that such mesenchymal stem cells contribute to the formation of blood vessels in the heart. Thus, Applicants have proven the principle that one can repair or regenerate blood vessels in the heart by administering mesenchymal stem cells. The Examiner has provided no evidence, other than sheer speculation, that methods of administration other than direct administration of the mesenchymal stem cells to the heart would not be effective in repairing or regenerating blood vessels in the heart. The Examiner therefore, has not met his burden in showing that methods of administration, other than direct administration of the mesenchymal stem cells to the heart, would not be enabled. Thus for the above reasons and others, Claims 12-21 are enabled in accordance with 35 U.S.C. 112, first paragraph, and it is

therefore respectfully requested that the rejection under 35 U.S.C. 112, first paragraph, be reconsidered and withdrawn.

For the above reasons and others, this application is in condition for allowance, and it is therefore respectfully requested that the rejections be reconsidered and withdrawn and a favorable action is hereby solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Raymond J. Lillie". The signature is fluid and cursive, with the first name "Raymond" being more prominent than the last name "Lillie".

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